

Serial No.: 09/890,387
Group Art Unit No.: 3728

REMARKS

This Amendment is made in response to the Final Action mailed August 27, 2003. A request for a three-month extension of time accompanies this Amendment. In addition, a Notice of Appeal is enclosed. Claim 16 has been amended. New claim 31 has been added and is directed to a specific embodiment of the invention, support for which can be found in the specification and claims as originally filed. Accordingly, claims 16 and 18-31 are pending in this application. No new matter has been added by the amendments to the claims. Entry of the amendments and favorable reconsideration and withdrawal of the objections to and rejections of this application are respectfully requested in view of the above amendments, and further, in view of the following remarks. Applicants submit that the amendments herein place the claims into condition for allowance, or in better condition for appeal.

Claim Rejections 35 U.S.C. § 103

Claim 16 and its dependent claims 20 and 30 have been rejected under 35 U.S.C. §103(a), as being unpatentable in view of U.S. Patent 5,516,006, issued May 14, 1996, to Meshberg ("Meshberg") in view of U.S. Patent 5,788,076, granted August 4, 1998, to Simmons ("Simmons"). Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 16 has been amended in order to clarify that the medicament is in contact with the inner wall and that the label is applied by an adhesive, and that there is a space empty of medicament content between the walls.

The teaching of Meshberg was reviewed and assessed in the Applicant's previous response, filed June 2, 2003. Meshberg Fig. 1 discloses a nasal spray container which is partly double-walled (16,31), but there is no reference to the problem of seepage through the container wall as addressed by the present invention, and in fact this could not occur in Meshberg's container as the medicament is contained in an inner container 12. Therefore, Meshberg is essentially a triple-walled container comprising the double-walled outer container 11 within which is enclosed the container 12. The container of Meshberg does not have a label attached thereto.

Simmons discloses a can or bottle, specifically disclosed as being made of a metallic material (see, col. 1, lines 22-23), though plastic, glass or cardboard are suggested (see, col. 2, lines 10-11 and col. 5, lines 6-7) upon which information is printed, and over which is applied a wrapper upon which information is printed to act as a promotional label. Specifically a typical metal drinks can is disclosed. A preferred type of label is a shrink-wrapped sleeve (see, col. 2, lines 17-18), but the wrapper may be "adhered" to the container (see, col. 2, line 22).

Serial No.: 09/890,387
Group Art Unit No.: 3728

The Examiner alleges that it would be obvious to provide the container of Meshberg with a label as taught by Simmons to promote sale. This allegation is respectfully traversed.

First, medicaments, e.g., of the type contemplated in the present invention are not normally the subject of sales promotions of the type envisaged in Simmons col. 1, lines 50-61. Simmons appears to contemplate application of the label to containers such as containing Cola-type consumer drinks, which are frequently promoted. Therefore, Simmons belongs to a field of art that would not be considered by the person of ordinary skill in the medicament art, and therefore the solution offered by Simmons would not be considered for use with a medicament container.

Second, the problem addressed by the present invention (see, page 2, lines 3-6) is that of permeation of the label adhesive through the permeable wall material of a container of a medicament to contaminate the contents, and permeation of the solvent contents of the container in the opposite direction to affect the label. This problem is not encountered by Meshberg because the medicament is contained within the inner container 12, and so does not contact the inner wall surface 18 of the container 11. There is nothing in Meshberg to suggest that the inner container 12 could be absent so that the medicament contacts the surface 18. Without inventive activity all that the combination of Meshberg and Simmons could lead to is a "triple-walled" container of a double outer wall 16,31 and the third inner wall of the container 12. Inventive activity in the present invention has lead to the realization that by positioning any label on the outer wall as claimed, the enclosure bounded by the inner wall may be used in direct contact with the medicament.

Claims 22-29 are alleged obvious over Meshberg in view of Simmons and further in view of WO 98/14189, published April 9, 1998, to Henkel ("Henkel"). Henkel discloses various formulations of the drug substance Mupirocin, but discloses no types of container or dispenser for these formulations. Therefore as parent claim 16 has been shown to be inventive over Meshberg and Simmons, there is nothing in Henkel to suggest the present claimed container.

Claims 16 and 18-21 are alleged obvious over U.S. Patent 2,494,456, issued January 10, 1950, to Still ("Still") in view of Simmons. Still discloses a double-walled container of which the only specifically disclosed construction material is glass (see, col. 1, line 29). Moreover the space between the two walls also contains a medicament 22 which may be a liquid (see, col. 2, line 22) and which in the drawings appears to be shown as a liquid. The Examiner alleges that it would have been obvious to apply the label of Simmons to the container of Still.

As Still requires that the space between the walls contains medicament, the limiting feature of the present amended claims that the space between the walls is empty of medicament content is not disclosed or suggested by Still. Since the purpose of Still is to

Serial No.: 09/890,387
Group Art Unit No.: 3728

enable the two respective substances in the inner compartment and between the walls to be mixed, Still leads away from this limiting feature. Therefore, if the label of Simmons were applied to the container of Still without the inventive activity of the present invention that the empty space between the walls can be used to avoid permeation, the present invention is not achieved.

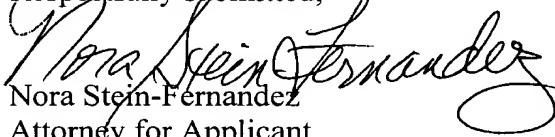
The Examiner alleges that the label of Simmons could be applied to parts of the outer wall of Still above the fluid line to thereby arrive at the present invention. This would be contrary to the present invention because it is self-evident that liquid content between the walls of Still might splash e.g., during transit, onto areas of the outer wall opposite the label, or the container of Still might be stored on its side so that liquid content between the walls remained in these areas for a long time.

Claims 22-29 are alleged obvious over Still in view of Simmons and further in view of Henkel. Henkel discloses various formulations of the drug substance Mupirocin, but discloses no types of container or dispenser for these formulations. Therefore, as parent claim 16 has been shown to be inventive over Still and Simmons, there is nothing in Henkel to suggest the claimed container.

Based upon the foregoing comments, Applicant urges that the claims are in condition for allowance, and are not made obvious by any fair combination of Meshberg, Still, Simmons or Henkel. One of skill in the art would not have been motivated to combine the teachings of the documents cited and modify those teachings to arrive at the instant invention.

In view of the foregoing, favorable reconsideration of claim 16, favorable consideration of new claim 31 and allowance of this application with claims 16 and 18-31 are earnestly solicited.

Respectfully submitted,


Nora Stein-Fernandez
Attorney for Applicant
Registration No. 36,689

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-5044
Facsimile (610) 270-5090
n:\ns\cpatapps\C70376\Amendment February 2004.doc